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April 30, 2004

BY FACSIMILE

Paul Schmidt
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Re: Oxycontin Litigation

Dear Mr. Schmidt:

Per our conversation of today, I am faxing you a copy of the Complaint we filed on behalf of the Local 1199 National Benefit Fund. Please advise if you are willing to accept service on behalf of your client in this matter.

Thank you for your cooperation.

Very truly yours,


Joseph Lipofsky, Esq.

cc: Hollis Salzman, Esq.

CIVIL COVER SHEET

04 CV 3093

JS 44C/SDNY
REV. 1/97
WEB 4/99

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for use of the Clerk of Court for the purpose of initiating the civil docket sheet.

PLAINTIFFS

LOCAL 1199 NATIONAL BENEFIT FUND FOR HEALTH
AND HUMAN SERVICES EMPLOYEES

DEFENDANTS

PURDUE PHARMA L.P., THE PURDUE FREDERICK
COMPANY, THE P. LABORATORIES, INC., THE
PURDUE PHARMA COMPANY, et al.

ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

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ATTORNEYS (IF KNOWN)

CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE)

Plaintiff, on its own behalf and on behalf of all third party payors, brings this action against Defendants alleging that Defendants, by monopolizing the market for oxycodone hydrochloride and generic bioequivalents of OxyContin, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 1, and in violation of Section 16 of the Clayton Act, 15 U.S.C. § 26, and seeks declaratory and injunctive relief.

Has this or a similar case been previously filed in SDNY at any time? No ☐ Yes ☒ Judge Previously Assigned: Sidney H. Stein

If yes, was this case Vol. ☐ Invol. ☐ Dismissed. No ☒ Yes ☐ If yes, give date: & Case No.:

(PLACE AN [x] IN ONE BOX ONLY)

NATURE OF SUIT

ACTIONS UNDER STATUTES

CONTRACT	TORTS		FORFEITURE/PENALTY		BANKRUPTCY		OTHER STATUTES	
[110 INSURANCE [120 MARINE [130 MILLER ACT [140 NEGOTIABLE INSTRUMENT [150 RECOVERY OF OVERPAYMENT & ENFORCEMENT OF JUDGMENT [151 MEDICARE ACT [152 RECOVERY OF DEFAULTED STUDENT LOANS (EXCL. VETERANS) [153 RECOVERY OF OVERPAYMENT OF VETERANS BENEFITS [180 STOCKHOLDERS SUITS [190 OTHER CONTRACT [195 CONTRACT PRODUCT LIABILITY	PERSONAL INJURY [310 AIRPLANE [315 AIRPLANE PRODUCT LIABILITY [320 ASSAULT, LIBEL & SLANDER [330 FEDERAL EMPLOYERS' LIABILITY [340 MARINE [345 MARINE PRODUCT LIABILITY [350 MOTOR VEHICLE [355 MOTOR VEHICLE PRODUCT LIABILITY [360 OTHER PERSONAL INJURY	PERSONAL INJURY [362 PERSONAL INJURY - MED MALPRACTICE [365 PERSONAL INJURY PRODUCT LIABILITY [368 ASBESTOS PERSONAL INJURY PRODUCT LIABILITY PERSONAL PROPERTY [370 OTHER FRAUD [371 TRUTH IN LENDING [374 OTHER PERSONAL PROPERTY DAMAGE [386 PROPERTY DAMAGE PRODUCT LIABILITY	[810 AGRICULTURE [820 FOOD & DRUG [825 DRUG RELATED SEIZURE OF PROPERTY [830 LIQUOR LAWS [840 RR & TRUCK [850 AIRLINE REGS. [860 OCCUPATIONAL SAFETY/HEALTH [880 OTHER LABOR [1710 FAIR LABOR STANDARDS ACT [1720 LABORMGT RELATIONS [1730 LABORMGT REPORTING & DISCLOSURE ACT [1740 RAILWAY LABOR ACT [1760 OTHER LABOR LITIGATION [1791 EMP. RET INC SECURITY ACT	[422 APPEAL 28 USC 158 [423 WITHDRAWAL 28 USC 157 PROPERTY RIGHTS [820 COPYRIGHTS [850 PATENT [840 TRADEMARK SOCIAL SECURITY [861 MA (1985FF) [862 BLACK LUNG (922) [863 DMC (405(g)) [864 BHW (405(g)) [1954 SSNO TITLE XVI [865 RSI (405(g)) FEDERAL TAX SUITS [870 TAXES [871 IRS-THIRD PARTY 20 USC 7609	[1400 STATE REAPPORTIONMENT [419 ANTI TRUST [430 BANKS & BANKING [460 COMMERCE/C RATES/ETC [460 DEPORTATION [470 RACKETEER INFLUENCED & CORRUPT ORGANIZATION ACT (ROCA) [850 SELECTIVE SERVICE [850 SECURITIES/COMMODITIES/EXCHANGE [875 CUSTOMER CHALLENGE-12 USC 5410 [1591 AGRICULTURE ACTS [1692 ECONOMIC STABILIZATION ACT [1693 ENVIRONMENTAL MATTERS [1694 ENERGY ALLOCATION ACT [1695 FREEDOM OF INFORMATION ACT [1696 APPEAL OF FEE DETERMINATION UNDER EQUAL ACCESS TO JUSTICE [1950 CONSTITUTIONALITY OF STATE STATUTES [1699 OTHER STATUTORY ACTIONS			
REAL PROPERTY	ACTIONS UNDER STATUTES		PRISONER PETITIONS					
[1210 LAND CONDEMNATION [1220 FORECLOSURE [1230 RENT LEASE & EJECTMENT [1240 TORTS TO LAND [1246 TORT PRODUCT LIABILITY [290 ALL OTHER REAL PROPERTY	CIVIL RIGHTS [441 VOTING [442 EMPLOYMENT HOUSING [443 ACCOMMODATIONS [444 WELFARE [440 OTHER CIVIL RIGHTS	[1510 MOTIONS TO VACATE SENTENCE 20 USC 2254 [1530 HABEAS CORPUS [1535 DEATH PENALTY [1540 MANDAMUS & OTHER [1550 CIVIL RIGHTS [1656 PRISON CONDITION						

This case is related to the Patent and Antitrust cases pending before Judge Sidney H. Stein between the Defendant herein, Purdue (Plaintiff in 00 Civ 8029) and Endo Pharmaceuticals (Defendant in 00 Civ 8029); This case concerns the same underlying factual and legal issues as that case; this case is also related on all points to UFCW v Purdue et al 04-CV-00122 also previously assigned to Judge Stein.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOCAL 1199 NATIONAL BENEFIT FUND :
FOR HEALTH AND HUMAN SERVICES :
EMPLOYEES, on behalf of itself and all others:
similarly situated, :

Plaintiff, :

v. :

PURDUE PHARMA L.P., THE PURDUE :
FREDERICK COMPANY, THE P.F. :
LABORATORIES, INC., THE PURDUE :
PHARMA COMPANY, ABBOTT :
LABORATORIES, AND :
EUROCELTIQUE S.A., :

Defendants. :
x

04-CV- 3093

JURY TRIAL DEMANDED

Plaintiff, on behalf of itself and all others similarly situated, hereby seeks damages, other monetary relief and equitable relief for Defendants' violations of federal and state antitrust laws, state consumer protection and deceptive acts and practices laws, and state common law principles of unjust enrichment. Plaintiff alleges, upon knowledge as to itself and its own acts, and upon information and belief as to all other matters, as follows:

1. This litigation arises from a series of actions undertaken by defendants Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company, (collectively "Purdue"), Abbott Laboratories, ("Abbott"), and Euroceltique S.A., ("Euroceltique") (collectively, "Defendants"), to unlawfully obtain and maintain their monopoly on controlled-release oxycodone hydrochloride prescription tablets ("oxycodone

hydrochloride"). In 2003, approximately 7 million prescriptions were written for OxyContin, the brand name of oxycodone hydrochloride, earning Purdue approximately \$1.27 billion in sales. Oxycodone hydrochloride is an opioid analgesic prescribed to treat moderate to severe pain.

2. Purdue obtained exclusive selling rights of oxycodone hydrochloride by virtue of a series of anticompetitive, deceptive and unlawful actions that enabled it to receive patents related to oxycodone hydrochloride. On January 5, 2004, the Southern District of New York declared the patents invalid, because of Purdue's inequitable and unlawful conduct in obtaining such patents, and enjoined Purdue from enforcing them. In the absence of Purdue's unlawful and inequitable actions, generic versions of OxyContin could have been available for sale as early as December 1995.

3. Purdue improperly maintained its monopoly on the oxycodone hydrochloride market through the enforcement of illegally-obtained patents covering the drug. Purdue's misrepresentations regarding the scope of its patent rights led the U.S. Food and Drug Administration ("FDA") to list patents in the Orange Book as protecting their monopoly on oxycodone hydrochloride.

4. Purdue's conduct has had a far-ranging impact on end-payors (consumers and third-party payors) across the United States. The laws governing pharmaceutical products are meant to balance the competing policy goals of providing new drug innovators an economic return on their investments while also ensuring end-payor access to additional and more affordable generic versions of brand-name drugs. By misrepresenting the nature and scope of its patents, Purdue effectively forced end-payors to continue to pay Defendants monopoly prices for oxycodone hydrochloride prescription products. Purdue receives more than \$ 1.26 billion annually in revenues from the sale of OxyContin.

5. In furtherance of the monopoly obtained by fraud and enabling the imposition of super-monopolistic prices, Purdue and Abbott and Euroceltique have engaged in aggressive false and misleading advertising. This co-promotion and licensing arrangement increased defendants' ability to charge inflated prices, further entrenched the monopoly and injured Plaintiff and the Class by forcing them to pay higher prices than would have been chargeable in the absence of the monopoly and the predatory advertising.

I. NATURE OF ACTION

6. Plaintiff brings its claims on behalf of all third-party payors, who purchased, paid for or reimbursed for a form of oxycodone hydrochloride other than for resale from at least December 1995, to the present.

7. This action is brought under federal and state antitrust laws, state consumer protection laws, and state common law and seeks damages and other declaratory and injunctive relief. As a result of their unlawful acts, Defendants have: (1) unreasonably restrained, suppressed and eliminated competition in the market for oxycodone hydrochloride; (2) illegally obtained and maintained their monopoly in the market for oxycodone hydrochloride; and (3) fixed, raised, maintained and stabilized the price of oxycodone hydrochloride at supra-competitive levels.

8. In Count I, Plaintiff, on its own behalf and on behalf of all third party payors, brings this action against Defendants alleging monopolization of, and an attempt to monopolize, the market for oxycodone hydrochloride and generic bioequivalents of OxyContin, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and seeks declaratory and injunctive relief.

9. Count II is brought by Plaintiff, on behalf of itself and on behalf of all third party payors, who purchased, paid for or reimbursed for OxyContin in Arizona, California, the District

of Columbia, Florida, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia and Wisconsin (the "Indirect Purchaser States").

10. Count III is brought by Plaintiff, on behalf of itself and on behalf of all third party payors, who purchased, paid for or reimbursed for OxyContin in Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and West Virginia, in violation of those states' unfair competition or deceptive acts and practices statutes (the "Consumer and Deceptive Practices Statutes States").

11. Count IV is also brought by Plaintiff, on behalf of itself and on behalf of all third party payors, who purchased, paid for or reimbursed for OxyContin, seeking a constructive trust and disgorgement of the unjust enrichment of Defendants.

II. PARTIES

A. Plaintiff

12. Local 1199 National Benefit Fund for Health and Human Services Employees ("Plaintiff" or "NBF") is located at 330 West 42nd Street, New York, New York 10036 and is an "employee welfare benefit plan" and an "employee benefit plan" within the Employee Retirement Income Security Act (ERISA), 29 USC §§1002(1), 1002(3), 1003(a). As such, Plaintiff is a legal entity entitled to bring suit in its own name pursuant to 29 USC §1132(d). Plaintiff is a not-for-profit trust, sponsored by and administered by a voluntary Board of

Trustees, established and maintained to provide comprehensive health care benefits to participants, who are entitled to benefits under various collective bargaining agreements. Plaintiff has paid all or part of the cost of its participants' purchases of OxyContin at supra-competitive prices during the Class Period. Unless Defendants' violations of the federal antitrust laws, state antitrust and/or consumer protection laws and common law unjust enrichment are enjoined by the Court, the Plaintiff and the Class will continue to pay or reimburse for OxyContin at supra-competitive prices. During the Class Period, the NBF has paid more for OxyContin by reason of Defendants' unlawful monopolization, deceptive acts and practices, and attempts to thwart or restrict generic competition for OxyContin.

(a) Defendants

13. Purdue Pharma L.P., The Purdue Frederick Company, and The Purdue Pharma Company have their headquarters at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. The P.F. Laboratories, Inc. is located at 700 Union Boulevard, Totowa, NJ 07512. Purdue is known for its pioneering research on chronic pain, and has been providing prescription and non-prescription products for over fifty years. Purdue's annual revenue is \$ 1.8 billion.

14. Throughout the class period, Purdue manufactured and sold substantial quantities of OxyContin in a continuous flow of interstate trade and commerce, and Purdue's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

15. The acts alleged in this Complaint to have been done by Purdue were authorized, ordered and performed by its officers, directors, agents, employees, representatives or subsidiaries while engaged in the management, direction, control or transaction of their business affairs.

16. Abbott Laboratories is headquartered at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500. Abbott is a diversified health care company that discovers, develops, manufactures and markets products and services in the areas of pharmaceuticals, nutritionals, hospital products and diagnostics.

17. During the class period, as hereinafter defined, Abbott co-promoted OxyContin with Purdue in a continuous flow of interstate trade and commerce, and Abbott's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

18. The acts alleged in this Complaint to have been done by Abbott were authorized, ordered and performed by its officers, directors, agents, employees, representatives or subsidiaries while engaged in the management, direction, control or transaction of their business affairs.

19. Euroceltique S.A., is located at 122 Boulevard De La Petrusse Luxembourg.

20. During the class period, each of the relevant patents was assigned to Euroceltique, and Euroceltique's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

21. The acts alleged in this Complaint to have been done by Euroceltique were authorized, ordered and performed by its officers, directors, agents, employees, representatives or subsidiaries while engaged in the management, direction, control or transaction of their business affairs.

22. Various other persons, partnerships, sole proprietors, firms, corporations and individuals not named as defendants in this lawsuit, and individuals, the identities of which are presently unknown, may have participated as co-conspirators with Purdue in the offenses alleged

in this complaint, and may have performed acts and made statements in furtherance of the alleged conspiracy.

III. JURISDICTION AND VENUE

23. Subject matter jurisdiction is proper pursuant to 28 U.S.C. §§ 1331, 1332, 1337 and 1367. The amount in controversy as to the claims of each named plaintiff and each of the other class members exceeds the sum or value of \$75,000, exclusive of interest and costs, as each class member has a common and integrated interest in Defendants' ill-gotten gains, for which the class seeks the remedy of disgorgement.

24. Venue is proper under 28 U.S.C. §§ 1391(b) and (c), 28 U.S.C. § 1407 and 15 U.S.C. § 22.

IV. CLASS ACTION ALLEGATIONS

25. Plaintiff brings this action on its own behalf and, under Rule 23(b)(2) of the Federal Rules of Civil Procedure, with respect to declaratory and equitable relief sought herein, and Rule 23(b)(3) of the Federal Rules of Civil Procedure, with respect to the damages and other monetary relief sought herein, as a representative of the Class of Third Party Payors defined as follows:

With respect to Counts I and IV, all third-party payors (including self-funded government entities) throughout the United States and its territories that purchased, paid for or reimbursed for OxyContin for a purpose other than for resale, at any time during the period from December 1995, the exact date being unknown, to the present (the "Class Period"). Excluded from the Class is any entity that purchased OxyContin directly from Defendants. For purposes of the Class definition, entities purchased, paid for, or reimbursed for OxyContin if they paid some or all of the purchase price ("Third Party Payor Class" or "Class");

With respect to Count II, a Sub-Class consisting of all third-party payors, including self-funded government entities that purchased, paid for or reimbursed for OxyContin in the "Indirect Purchaser States" (the "Indirect Purchaser Class"); and,

With respect to Count III, a Sub-Class consisting of all third-party payors, including self-funded government entities that purchased, paid for or reimbursed for OxyContin in the "Consumer and Deceptive Practices Statutes States" (the "Consumer and Deceptive Practices Statutes Class").

26. Excluded from the Class and the Sub-Classes listed above are Defendants and their respective subsidiaries and affiliates, and all government entities, other than self-funded government entities that paid for all or part of the purchase price for OxyContin.

27. The Class is so numerous that joinder of all members is impracticable. While the exact size of the Class is unknown to Plaintiff at the present time, the members of the Class are believed to number in the thousands.

28. Common questions of law and fact exist as to all members of the Class. Among those questions are the following:

(a) whether Defendants unlawfully monopolized the United States market for oxycodone hydrochloride prescription drug products;

(b) whether Defendants' conduct delayed the marketing of generic OxyContin products in the United States from at least December 1995, the exact date being unknown, to the present;

(c) whether Defendants' unlawful conduct caused Plaintiff and the other Class members to pay more for oxycodone hydrochloride products than they otherwise would have paid;

(d) whether Defendants' conduct, as alleged herein, violated the state antitrust and unfair trade practices laws set forth in Counts II and III herein;

(e) whether Defendants had monopoly power in the relevant market for purposes of Plaintiff's monopolization claims;

(f) whether Defendants unjustly enriched themselves to the detriment of Third Party Payors, thereby entitling Plaintiff and the other Class members to disgorgement of all benefits derived therefrom;

(g) the appropriate measure of damages incurred by the Class; and

(h) whether the Class is entitled to injunctive and other equitable relief.

29. These and other questions of law and fact are common to the members of the Class and predominate over any questions affecting only individual members.

30. Plaintiff's claims are typical of the claims of the members of the Class because Plaintiff and all other Class members sustained damages in the same way, as a result of Defendants' wrongful conduct complained of herein, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

31. Plaintiff will fairly and adequately protect the interests of the other Class members. Plaintiff has retained counsel who is experienced in class action and antitrust litigation, and Plaintiff has no interest in this litigation that is adverse to or in conflict with the interest of the other members of the Class.

32. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The damages suffered by many members of the Class are expected to be relatively small, so that the expense and burden of prosecuting an antitrust damages case such as this one will almost certainly preclude individual litigation by such members. Plaintiff knows of no difficulty that will be encountered in the management of this litigation that will preclude its maintenance as a class action.

V. OPERATIVE FACTS

33. The statute regulating the manufacture and distribution of drugs and medical devices in the United States is the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. (the "FD&C Act"). Under the FD&C Act, approval by the FDA, the governmental body charged with regulation of the pharmaceutical industry, is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 355(a). Premarket approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 355(b) of the FD&C Act demonstrating that the drug is safe and effective for its intended use.

34. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the right to exclude others from making, using or selling that new drug in the United States for the duration of the patents, plus any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch-Waxman Act").

35. Pursuant to 21 U.S.C. § 355(b), in its NDA the pioneer drug manufacturer must list all patents that claim the drug for which FDA approval is being sought, or that claim a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

36. Once the NDA is approved, any claimed patents are listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations. This publication is commonly called the "Orange Book."

37. Pursuant to 21 U.S.C. § 355(c)(2), if, after its NDA is approved, the pioneer drug manufacturer is issued a new patent that claims the drug or methods of its use, the company must supplement its NDA by listing such new patent within 30 days of issuance, whereupon the FDA

publishes the new patent in a supplement to the Orange Book. The FDA is required to accept as true patent information it obtains from patent holders, such as whether a patent covers a particular drug product. If an unscrupulous patent holder is willing to provide false information to the FDA to delay the onset of generic competition, the FDA is powerless to stop it.

38. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a doctor who writes a prescription specifying the drug, which must be purchased from a licensed pharmacist. Generally, the pharmacist must, in turn, fill the prescription with the drug specified by the physician unless a generic version is available that has been approved by the FDA for substitution as bioequivalent.

39. Generic drugs are drugs that the FDA has found to be bioequivalent to their corresponding brand-name drug. A generic drug provides the identical therapeutic benefits as its brand-name counterpart.

40. Generic drugs are invariably priced substantially below the branded drugs to which they are bioequivalent. Typically, the first generic drug is sold at a substantial discount to the brand name drug, followed by steeper discounts as more companies begin selling the generic. The beneficiaries of this competition are the patients and third-party payors who pay the retail price of drugs sold by pharmacies.

41. Virtually all third-party payors encourage patients to use generic drugs by, among other things, requiring lower co-payments from members who receive generics.

42. Moreover, if a lower-priced generic version of a brand-name drug exists, and the physician has not specifically indicated on the prescription "dispense as written" (or a similar

instruction), and the consumer is covered by a typical third-party payor plan, the pharmacist will substitute, or at least offer to substitute, the generic drug.

43. The branded drug generally loses substantial sales to generics within a relatively short time, primarily as a result of cross-overs to lower-priced generics by patients, including patients in third-party payor plans.

44. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand-name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA") pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the brand-name drug. One of Congress's central goals in enacting the Hatch-Waxman Act was "to bring generic drugs onto the market as rapidly as possible." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

45. The Hatch-Waxman Act permits ANDA applicants to perform all necessary testing, submit an application for approval, and receive tentative approval before the relevant patents expire. Prior to the Hatch-Waxman Act, a generic applicant had to wait until all patents had expired prior to beginning the approval process or otherwise face an infringement suit.

46. OxyContin received FDA approval in December 1995. Purdue owns the patents ostensibly protecting OxyContin, i.e., U.S. Patent No. 5,549,912, (the "912" patent); U.S. Patent No. 5,508,042, (the "042" patent), and U.S. Patent No. 5,656,295 (the "295" patent); as well as the related "parent" patent, U.S. Patent No. 5,266,331 (the "331" patent).

47. In July 2000, Endo Pharmaceuticals, Inc. ("Endo") filed ANDA No. 75-923, requesting FDA approval to sell a generic version of OxyContin in the 40 mg strength. As part of its ANDA application, Endo certified that its sale of a generic version of OxyContin would

not infringe Purdue's relevant patents, or that the patents were invalid. Endo later amended its ANDA twice, such that it also sought approval to market oxycodone hydrochloride in the 10, 20, and 80 mg strengths.

48. Under the applicable provisions of the Hatch-Waxman Act, Purdue sued Endo and Endo Pharmaceuticals Holdings Inc. for patent infringement, alleging that Endo's ANDA violated claims 1 to 4 of the '912 patent; claims 1 and 2 of the '042 patent, and claims 1 to 4 and 6 to 10 of the '295 patent.

49. Because this suit was filed within 45 days of Endo's notification to Purdue of its certification, the FDA was legally prevented from approving Endo's ANDA for 30 months unless there was an earlier final court decision that the relevant patents were invalid. Thus, when the FDA granted approval of Endo's ANDA for four strengths of OxyContin on July 31, 2002, the approval was only tentative.

50. Endo counterclaimed that Purdue had violated the federal antitrust laws through misuse of the relevant patents, as well as obtaining such patents on the basis of inequitable conduct, and sought declaratory judgment that the patents were invalid and unenforceable.

51. In June 2003, the patent issues in Purdue's lawsuit were tried in the United States District Court for the Southern District of New York without a jury. During the course of this litigation, it was held that Purdue had made a deliberate decision to misrepresent material facts to the United States Patent and Trademark Office, ("PTO"), in connection with the patents it had filed related to OxyContin.

52. Specifically, the '912, '042, and '295 patent specifications repeat the fact that it was claimed to have been "surprisingly discovered" that the controlled release oxycodone formulation controls pain in approximately 90 % of patients with a significantly smaller dosage

than required for opioid analgesics in general. In other words, Purdue had informed the PTO that OxyContin was unique because a small dose of it was effective.

53. In fact, OxyContin's creator, Dr. Robert F. Kaiko, ultimately admitted at trial that he had done no clinical studies and had "no scientific proof" to support these material statements at the time of filing the '912 patent. Instead, Dr. Kaiko relied on his "insight," for some of which he acknowledged there was no supporting data.

54. Purdue produced no documents to contravene this testimony. As an alternative, Purdue argued that a "discovery" can include purely mental acts such as Dr. Kaiko's insight.

55. Moreover, internal Purdue documents written at the time of the relevant patent prosecution indicate, inter alia, that "[w]hile the theoretical argument may be relatively strong" as to the claims of reduced dosage and ease of titration of oxycodone hydrochloride, "an acceptance of a priority program for controlled-release oxycodone should not assume that all these claims can be demonstrated." (Emphasis added.)

56. Additional documents indicate that Purdue executives believed the company's claims for the drug "weren't anywhere close" to being proved and were "clearly Bob Kaiko's vision."

57. On January 5, 2004, the United States District Court for the Southern District of New York held that the patents at issue were rendered unenforceable by virtue of Purdue's inequitable conduct before the PTO during their prosecution. See *Purdue Pharma L.P. v. Endo Pharms. Inc.*, No. 00 Civ. 8029 (S.D.N.Y. Jan. 5, 2004). The Court found that "Purdue made a deliberate decision to misrepresent to the PTO a 'theoretical argument' and an 'expectation' as a precisely quantified 'result' or 'discovery.'" Further, Purdue "cannot in good faith contend that it did not know that this 'discovery'... was material information."

58. After a trial on the merits, the Court concluded that “[t]he record as a whole reflects a clear pattern of intentional misrepresentation of a material fact,” and thus, the “repeated intentional misrepresentations... so serious as to warrant the severe sanction of holding the patents unenforceable.” (Internal quotations and citation omitted.)

59. In a recent statement, Robin Hogen, a spokesperson for Purdue Pharma, said the company planned to appeal this decision. In view of this impending appeal, Endo has not yet decided to market a generic version of OxyContin.

60. Because of its inequitable conduct before the PTO, resulting in the issuance to it of patents to which it was not lawfully entitled, Purdue has never faced generic competition in the oxycodone hydrochloride market. In addition, these unlawfully obtained patents enabled it to maintain sham litigation which it instituted to enforce such patents. This litigation has delayed FDA final approval of generic OxyContin products. Endo has tentative approval from the FDA to market generic OxyContin in the 10, 20, 40, and 80 mg strengths (issued July 31, 2002); Impax Laboratories has tentative approval to market generic OxyContin in the 10, 20, and 40 mg strengths (issued September 4, 2003), and in the 80 mg strength (issued December 23, 2003); and Teva Pharmaceuticals has tentative approval to market generic OxyContin in the 80 mg strength (issued September 29, 2003). None of these companies, however, has been granted final approval by the FDA to market oxycodone hydrochloride due to the Purdue’s sham litigation and its other unlawful and improper conduct in connection therewith.

61. After Purdue fraudulently obtained the patent, Purdue began promoting OxyContin with a sales force of approximately 300 representatives in its Prescription Sales Division. Through a 1996 co-promotion agreement, Abbott Laboratories provided at least another 300 representatives, doubling the total OxyContin sales force. Abbott Laboratories’ 300

sales representatives actively promoted OxyContin to hospital-based anesthesiologists and surgeons and major hospitals, medical centers, and freestanding pain clinics. Because these contacts would often provide the inception of the pain treatment of the drug, such targeted promotion was instrumental in entrenching the prescription drug at the supra-competitive prices.

62. The General Accounting Office ("GAO") found that in marketing the drug, the promotional videos of Purdue and Abbott made unsubstantiated claims and minimized the dangers and addictiveness associated with the pain relief drug. The GAO also found that in 1998 Stamford, Connecticut-based Purdue Pharma failed to submit one of the videos to the FDA for review, as required, when the company started circulating it to thousands of doctors. On the 1998 video, a doctor says that less than one percent of people who take pain relief medication like OxyContin become addicted. That's a figure the FDA says has not been substantiated, the report said.

63. At the request of the GAO, the FDA looked at the later video and found it "appeared to make unsubstantiated claims regarding OxyContin's effect on patients' quality of life and ability to perform daily activities and minimized the risks associated with the drug.

64. The aggressive and fraudulent marketing of the drug, coupled with the undisclosed addictiveness expanded the monopoly power Defendants had over its pricing and furthered its sales.

VI. RELEVANT MARKET

65. During the Class Period, the relevant market was the manufacture and sale of oxycodone hydrochloride in the United States.

66. During the Class Period, Defendants' share of the relevant market was 100%, and they had and continue to have monopoly power in the relevant market during that time period.

VII. MARKET EFFECTS

67. The acts and practices of Purdue, as herein alleged, had the purpose and effect of restraining competition unreasonably and injuring competition by preventing the entry of generic OxyContin products into the relevant market. Purdue's fraudulent and exclusionary conduct unlawfully protected OxyContin from generic competition during the class period.

68. But for Purdue's illegal conduct, a generic competitor would have begun marketing a generic version of OxyContin as early as December 1995 or earlier.

69. Defendants' co-promotion and licensing arrangements enhanced and facilitated the imposition of super-monopolistic prices on end-payors.

70. If a generic competitor had been able to enter the relevant market and compete with Purdue and Abbott, End-Payors such as Plaintiff would have been free to substitute a lower-priced generic for the higher-priced brand name drug and the Class would have paid less for oxycodone hydrochloride products. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, there is a ready market for generic products because certain third-party payors of prescription drugs (e.g., managed care plans) encourage or insist on the use of generic drugs whenever possible. A generic product can quickly and efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year.

71. By preventing generic competitors from entering the market, Defendants injured Plaintiff and the other Class members in their business or property by causing them to pay more for oxycodone hydrochloride products than they otherwise would have paid. Defendants'

unlawful conduct deprived Plaintiff and other End-Payers of the benefits of competition that the antitrust laws and applicable state consumer protection laws were designed to preserve.

VII. FRAUDULENT CONCEALMENT

72. The running of any statute of limitations has been tolled by reason of Purdue's fraudulent concealment. Purdue actively concealed that it had procured its patents protecting OxyContin through inequitable conduct. The falsity of Defendants' marketing in furtherance of the monopoly was also undisclosed to Plaintiff and the Class.

73. Defendant's conduct and scheme was covert and was never disclosed to Plaintiff and members of the Class. On information and belief, Plaintiff and members of the Class were unaware of, and could not through due diligence have discovered, the existence of the unlawful methods by which the relevant patents were obtained.

COUNT I

DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

(On Behalf of the Third Party Payor Class)

74. Plaintiff incorporates by reference the preceding allegations.

75. Pursuant to United States patent laws, Purdue was given a monopoly over sales of oxycodone hydrochloride, but that monopoly was only lawful or proper so long as the drug, or a method of its use, was fully covered by valid, unexpired patents.

76. As described above, Purdue knowingly and willfully engaged in a course of conduct designed to establish a fraudulently obtained monopoly and Defendants agreed and conspired to extend that monopoly power. This course of conduct included, inter alia, engaging in inequitable conduct to obtain patent protection of OxyContin, and inducing the FDA to list the

patents in the Orange Book through submission of false patent information to the FDA and falsely and aggressively marketing the drug with materials not approved by the FDA that failed to disclose its addictive quality. The result of Defendants' unlawful conduct was to create a monopoly and extend it beyond the time period permitted by United States law.

77. During the Class Period, Defendants possessed monopoly power in the relevant market.

78. Defendants intentionally and wrongfully maintained their monopoly power in the relevant market in violation of Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2.

79. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of paying higher prices for oxycodone hydrochloride than they would have paid in the absence of that violation. Such injury is of the type antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

80. Plaintiff and members of the class are likely to purchase oxycodone hydrochloride again in the future.

81. There is a real and imminent threat that Defendants are continuing to restrict generic competition in the relevant market. Injunctive relief is therefore appropriate under Section 16 of the Clayton Act, 15 U.S.C. § 26.

82. Plaintiff seeks to enjoin Defendants from engaging in future anticompetitive practices concerning the manufacture, distribution or sale of OxyContin. Plaintiff does not seek damages under Count I.

COUNT II

**MONOPOLIZATION AND ATTEMPT TO MONOPOLIZE IN
VIOLATION OF LAWS OF INDIRECT PURCHASER STATES**

(On Behalf of the Indirect Purchaser Class)

83. Plaintiff incorporates by reference the preceding allegations.

84. Pursuant to United States patent laws, Purdue was given a monopoly over sales of oxycodone hydrochloride, but that monopoly was obtained by fraudulent and inequitable conduct.

85. As described above, Purdue knowingly and willfully engaged in a course of conduct designed to establish a fraudulently-obtained monopoly and Defendants agreed and conspired unlawfully to extend that monopoly power. This course of conduct included, inter alia, Purdue inducing the PTO to issue patents to it relating to OxyContin and the FDA to list such patents in the Orange Book through submission of false patent information and Defendants falsely and aggressively marketing the drug with materials not approved by the FDA that failed to disclose its addictive quality.

86. During the Class Period, Defendants possessed monopoly power in the relevant market.

87. Defendants' unlawful contracts, agreements, arrangements, and combinations in restraint of trade or commerce alleged herein, and attempts to monopolize, conspiracies to monopolize and monopolization of the relevant market alleged herein, violate the Indirect Purchaser States' antitrust and/or consumer protection laws as follows:

(a) Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1402, et seq., and the Constitution of the State of Arizona, Article 14, §15;

(b) California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, California Business and Professions Code §§ 16700, et seq. and the California Unfair Competition Act, California Business and Professions Code §§ 17200, et seq.;

(c) District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Restraint of Trade Act, D.C. Code §§ 28-4501, et seq.;

(d) Florida: The aforementioned practices by Defendants were and are in violation of the Florida Deceptive and Unfair Trade Practices Act, Chapter 501, Part II, et seq.;

(e) Hawaii: The aforementioned practices by Defendants were and are in violation of the Hawaii antitrust statute, Hawaii Revised Statutes, Chapter 480, §§ 480-1, et seq.;

(f) Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.1 et seq.;

(g) Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Unfair Trade and Consumer Protection Act, KSA §§ 50-101, et seq.;

(h) Kentucky: The aforementioned practices by Defendants were and are in violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110-310, et seq.;

(i) Louisiana: The aforementioned practices by Defendants were and are in violation of Louisiana Revised Statutes §§ 51:137, et seq.;

(j) Maine: The aforementioned practices by Defendants were and are in violation of the Maine Trade Regulation Law of 1954, 10 M.R.S.A. §§ 1101, et seq., and the Maine Unfair Trade Practices Act, 5 M.R.S.A. § 205-A, et seq.;

- (k) Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Consumer Protection Act, M.G.L Ch. 93A, et seq.;
- (l) Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, MCL §§445.771, et seq.;
- (m) Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Act of 1971, Minn. Stat. §§ 325D.49, et seq.;
- (n) Nebraska: The aforementioned practices by Defendants were and are in violation of the Nebraska antitrust statute, Neb. Rev. Stat. §§ 59-801, et seq.;
- (o) Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practice Act, Nev. Rev. Stat. §§ 53:598A, et seq.;
- (p) New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, et seq.;
- (q) New Jersey: The aforementioned practices by Defendants were and are in violation of the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1, et seq.;
- (r) New York: The aforementioned practices by Defendants were and are in violation of the New York Donnelly Act, GBL §§ 340, et seq. and/or New York General Business Law §349;
- (s) North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust law, N.C.G.S. §§ 75-1, et seq.;
- (t) North Dakota: The aforementioned practices by Defendants were and are in violation of North Dakota's antitrust law, North Dakota Cent. Code §§ 51-08.1, et seq.;
- (u) South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, SDCL ch. 37-1, et seq.;

(v) Tennessee: The aforementioned practices of Defendants were and are in violation the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, et seq., and the Consumer Protection Act of 1977, Tenn. Code Ann. §§ 47-18-101, et seq.;

(w) Vermont: The aforementioned practices of Defendants were and are in violation of Vermont antitrust law, Vermont Stat. §§ 2453, et seq.;

(x) West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, Chapter 47, Article 18, Section 1, et seq., West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-1-101, et seq.; and

(y) Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stats §§ 133.01, et seq.

88. Plaintiff and the members of the Indirect Purchaser Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of paying higher prices for controlled-release oxycodone hydrochloride prescription tablets than they would have paid in the absence of those violations. Their injury is of the type the antitrust and consumer protection laws of the above States and the District of Columbia were designed to prevent and flows from that which makes Purdue's conduct unlawful.

89. Plaintiff and the Class seek damages as permitted by law caused by Defendants' violations of these statutes.

90. Plaintiff and the Class seek multiple damages as permitted by law caused by Defendants' intentional and/or flagrant violations of these statutes.

91. Plaintiff and the Class seek injunctive and declaratory relief as permitted by law caused by Defendants' violations of these statutes.

COUNT III**DAMAGES UNDER APPLICABLE CONSUMER AND
DECEPTIVE TRADE PRACTICES UNDER STATE LAW**

(On Behalf of the Consumer and Deceptive Practices Statutes Class)

92. Plaintiff incorporates by reference the preceding allegations.

93. Purdue engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes when it engaged in a course of conduct designed to induce the PTO to grant it patents relating to OxyContin and the FDA to improperly list the applicable patents in the Orange Book, and thus prevent the FDA from granting final approval of pending applications of would-be competitors to market generic OxyContin in competition with OxyContin. Such FDA final approvals were delayed under the Hatch-Waxman Act, inter alia, because of Purdue's filing of sham patent infringement litigation. Thereafter, Purdue continued to engage in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices through the dissemination of a press release and through representations made to the FDA regarding the construction of the applicable patents. As a direct result of Purdue's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and the Class were deprived of the opportunity to purchase generic OxyContin beginning at least as early as December 1995.

94. After Purdue unlawfully and fraudulently obtained its OxyContin patent, Defendants thereafter falsely marketed the drug with materials not approved by the FDA and which materials glaringly failed to disclose and, indeed, minimized the drug's addictive quality.

95. Defendants incentivize their sales force to sell the drug at higher dosages, increasing the possibility for addiction and abuse.

96. Defendants detailing to doctors with respect to this drug included gifts and promotional gimmicks unprecedented for promotion of a Schedule II opioid.

97. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Alaska Stat. § 45.50.471 et seq.

98. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522 et seq.

99. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Ark. Code § 4-88-101 et seq.

100. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200 et seq.

101. Defendants have engaged in unfair competition or deceptive acts or practices or have made false representations in violation of Colo. Rev. Stat. § 6-1-105 et seq.

102. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b et seq.

103. Defendants have engaged in unfair competition or deceptive acts or practices in violation of 6 Del. Code § 2511 et seq.

104. Defendants have engaged in unfair competition or deceptive acts or practices or made false representations in violation of D.C. Code Ann. § 28-3901 et seq.

105. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Fla. Stat. § 501.201 et seq.

106. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Ga. Stat. § 10-1-392 et seq.

107. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Haw. Rev. Stat. § 480 et seq.

108. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Idaho Code § 48-601 et seq.

109. Defendants have engaged in unfair competition or deceptive acts or practices in violation of 815 Ill. Comp. Stat. § 505.1 et seq.

110. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Kan. Stat. Ann. § 50-623 et seq.

111. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110 et seq.

112. Defendants have engaged in unfair competition or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401 et seq.

113. Defendants have engaged in unfair competition or deceptive acts or practices in violation of 5 Me. Rev. Stat. Ann. § 207 et seq.

114. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Massachusetts General Laws Ch. 93A.

115. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Md. Com. Law Code § 13-101 et seq.

116. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Mich. Stat. § 445.901 et seq.

117. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Minn. Stat. § 8.31 et seq.

118. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Mo. Ann. Stat. § 407.010 et seq.

119. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Mont. Code § 30-14-101 et seq.

120. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601 et seq.

121. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903 et seq.

122. Defendants have engaged in unfair competition or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1 et seq.

123. Defendants have engaged in unfair competition or deceptive acts or practices in violation of violation of N.J. Rev. Stat. § 56:8-1 et seq.

124. Defendants have engaged in unfair competition or deceptive acts or practices in violation of N.M. Stat. § 57-12-1 et seq.

125. Defendants have engaged in unfair competition or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 et seq.

126. Defendants have engaged in unfair competition or deceptive acts or practices in violation of N.C. Gen. Stat. §§ 75-1.1 et seq.

127. Defendants have engaged in unfair competition or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01 et seq.

128. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01 et seq.

129. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Okla. Stat. 15 § 751 et seq.

130. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605 et seq.

131. Defendants have engaged in unfair competition or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1 et seq.

132. Defendants have engaged in unfair competition or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1 et seq.

133. Defendants have engaged in unfair competition or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10 et seq.

134. Defendants have engaged in unfair competition or deceptive acts or practices in violation of S.D. Code Laws § 37-241 et seq.

135. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Tenn. Code Ann. § 47-18-101 et seq.

136. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41 et seq.

137. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Utah Code § 13-11-1 et seq.

138. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Vt. Stat. § 2451 et seq.

139. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Va. Code § 59.1-196 et seq.

140. Defendants have engaged in unfair competition or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010 et seq.

141. Defendants have engaged in unfair competition or deceptive acts or practices in violation of W. Va. Code § 46A-6-101 et seq.

142. Plaintiff and members of the Consumer and Deceptive Practices Statutes Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Count. Their injury consists of paying higher prices for OxyContin than they would have paid in the absence of these violations. This injury is of the type the state consumer protection and deceptive practices statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT IV

UNJUST ENRICHMENT UNDER STATE LAW

(On Behalf of All Third Party Payors)

143. Plaintiff incorporates by reference the preceding allegations.

144. Defendants have benefited from Purdue's unlawful acts through the overpayments for OxyContin products by Plaintiff and other Class members and the increased profits resulting from such overpayments. It would be inequitable for Defendants to be permitted to retain the benefits or profits resulting from these overpayments, which were conferred by Plaintiff and the Class and retained by Defendants.

145. Even if the OxyContin patents were not obtained by the inequitable and unlawful conduct of Purdue, such patents were otherwise invalid and Plaintiff and the Class have, thus, made overpayments to Defendants as a result of such invalid patents.

146. Plaintiff and members of the Class are entitled to the establishment of a constructive trust consisting of the benefit to Defendants of such overpayments, from which Plaintiff and the other Class members may make claims on a pro-rata basis for restitution.

147. Plaintiff and members of the Class are entitled restitution from Defendants regardless of the lawfulness of Purdue's activity in obtaining patents relating to OxyContin.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court declare, adjudge and decree the following:

(a) That this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiff's claims for declaratory, equitable and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages and other monetary relief, and declaring Plaintiff as representative of the Class and its counsel as counsel for the Class;

(b) That the conduct alleged herein constitutes unlawful monopolization and an attempt to monopolize in violation of Section 2 of the Sherman Act, of the statutes of the Indirect Purchaser States set forth above, of the Consumer and Deceptive Practices Statutes set forth above, and the common law of unjust enrichment;

(c) That Plaintiff and the Class are entitled to any additional damages, penalties and other monetary relief provided by applicable law, including treble damages;

(d) That Plaintiff and each member of the Class are entitled to the amounts by which the Defendant has been unjustly enriched;

(e) That Defendant is enjoined from continuing the illegal activities alleged herein;

(f) That Plaintiff and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

(g) That Plaintiff and the Class are granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

JURY DEMANDED

Plaintiff demands a trial by jury of all issues so triable.

Dated: April 22, 2004
New York, New York

Respectfully submitted,

ZWERLING, SCHACHTER &
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